REMARKS

In this Amendment, Applicant has amended Claim 1 and added new Claims 20 – 21 to correct informalities and specify different embodiments of the present invention. It is respectfully submitted that no new matter has been introduced by the amended and added claims. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

DOUBLE PATENTING:

Claims 8 – 11, 13 – 17 and 19 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 – 3 of U.S. Patent No. 5,120,760. Claims 8 – 19 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 – 6 of U.S. Patent No. 4,753,964.

It is respectfully submitted that the claims of the present application are not obvious over the claims of U.S. Patent No. 5,120,760 and U.S. Patent No. 4,753,964. Under the U.S. patent law, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985), MPEP 804. Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries include consideration of the differences between the scope and content of the patent claim and the claim in the application at issue; and determine the level of ordinary skill in the pertinent art. Further,

those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970), MPEP 804. In addition, according to the U.S. patent law, the examiner's conclusion of obviousness should not be based on improper hindsight reasoning. Any judgement on obviousness should take into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and should not include knowledge gleaned only from applicant's disclosure. See *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971), MPEP 2145. X. A.

Applicant respectfully submits that the example picked by the Examiner is based on impermissible hindsight obtained ONLY from the Applicant's disclosure in the present application, NOT from the U.S. Pat. No. 5,120,760 and U.S. Pat No. 4,753,964. Therefore, the claimed invention is not obvious over the cited patent and the obvious-type double patenting rejection is improper. More specifically, US Pat. No. 4,753,964 simply states the use of essential fatty acids (EFAs) to treat these disorders, which can be in the absence of lithium used in most of the embodiment of the patent. Take one example that has no lithium (Capsules 1 – 2 in Example 2 of US Pat. No. 4,753,964), the ratio of n-3 to n-6 EFAs is 1:1 in capsule 2 (see the metabolic pathways of the acids on page 2 of the specification). For capsule 1, evening primrose oil is used, which is a conventional source of EFAs. Evening primrose oil is a blend of the n-6 EFAs and n-3 EFAs. EPA and DHA are n-s EFAs; DGLA and AA are n-6 EFAs. The ratio of EPA to the n-6 AA and DGLA present in evening primrose oil is 1:2 (50mg:50+50mg). This is far from the embodiments of the present invention, which requires that the EPA:n-6 EFAs ratio to be at least 3:1, if the n-6 EFAs are present. The present invention recognizes that the n-3 EPA or SA is more important than the n-6 in the context of treating the defined disorders. The Applicant draws the Examiner's attention to page 5 of the specification, where it is indicated that treatment with n-6 EFAs is less effective. In addition, Capsule 5 of Example 2 of U.S. Pat. 4,753,964 used lithium and the ratio of EPA to n-6 GLA is 25mg

to 40mg, which is far from the required ratio of the present invention. Especially, the new Claim 20 uses "consisting essentially of" that exclude the lithium compound.

The U.S. Pat. 4,753,964 indicated that there are particularly preferred essential fatty acids and listed some n-3 EFAs (including EPS) and some n-6 EFAs. However, this is not the disclosure of the method of using the EPA compositions as presently claimed, in which the EPA has to be at least 3 times more than n-6 EFAs, if present. The U.S. Pat. 4,753,964 indicated that the preferred source of oil is the evening primrose oil – the conventional available blend of n-6 and n-3 EFAs (see col. 2, lines 47 – 48). This obviously teaches away from the present invention. Therefore, Claims 8 – 19 are not obvious over Claims 1 – 6 of the U.S. Pat. 4,753,964.

Regarding the U.S. Pat. No. 5,120,760, it also uses evening primrose oil to treat tardive dyskinesia. As discussed above, it is high in n-6 EFAs and does not teach the 3:1 dominance of the EPA or SA as required in the claims of the present invention. In the examples disclosed on column 4 of the U.S. Pat. No. 5,120,760, there is no disclosure that EPA to n-6 EFAs ratio is at least 3:1. In Example 1 of column 6, there is a blend of evening primrose oil (as discussed above) and fish oil. This is high in n-6 EFAs (GLA). Example 2 has 200mh GLA and 200 EPA. Example 5 has only 50mg EPA and this is outweighted by the n-6 EFAs. There is no disclosure or suggestion that "the weight ratio of SA/EPA to said n-6 EFAs, if present, is not less than 3:1" as required in the claims of the present invention.

Therefore, the example picked by the Examiner with 7g of EPA, 2g of SA and 1g of GLA can not be envisioned by a person of ordinary skill in the art based on the teaching of U.S. Pat. No. 5,120,760 and U.S. Pat No. 4,753,964 at the time of the present invention. Such example is only picked because the Examiner uses hindsight obtained from the teaching of the present invention. Such hindsight is impermissible when evaluating the obviousness of an invention. Thus, the obviousness-type double patenting rejection is improper.

Accordingly, withdrawal of the double patenting rejection is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 102:

Claims 8 – 11 and 13 – 19 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by U.S. Pat. No. 5,120,760. Claims 8 and 12 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by and U.S. Pat No. 4,753,964.

Applicant traverses the rejection and respectfully submits that the presently claimed invention is not anticipated by the cited reference. As stated above, the example picked by the Examiner is not disclosed or suggested by U.S. Pat. No. 5,120,760 and U.S. Pat No. 4,753,964. There is not express disclosure of the example, nor inherent teaching of such example, because it is not necessary that the components of the EFAs are of the ratios in the example. Because the Examiner picks the example solely based on the hindsight of the present application, not the express or inherent teaching of the U.S. Pat. No. 5,120,760 and U.S. Pat No. 4,753,964, the anticipation rejection is improper.

Therefore, the newly presented claims are not anticipated by U.S. Pat. No. 5,120,760 and U.S. Pat No. 4,753,964, and the rejection under 35 U.S.C. § 102 (b) has been overcome. Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully requested.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

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